

REMARKS

The rejection has been considered at length. However, for the reasons set forth below, it is believed that the claimed subject matter would not have been rendered obvious by the combination of the cited references.

Claims 57-61 were pending and have been examined on the merits. Claim 57-58 and 60 have been cancelled, claims 59 and 61 have been amended hereinabove and claim 67 has been added. Support for new claim 67 can be found in the subject matter of cancelled claims 57 and 58 and on the specification on page 31, lines 1-4. No new matter has been added.

In this Final Office Action the claims are rejected as follows:

1. Claims 57-61 are rejected under 35 U.S.C. § 112, ¶1, as allegedly failing to comply with the written description requirement;
2. Claims 57-61 stand rejected under 35 U.S.C. § 103(a) as being obvious over Sweeney et al (hereinafter “Sweeney”) in combination with U.S. 5,747,536 to Cavazza (hereinafter “Cavazza”) and Ogawa et al (hereinafter “Ogawa”) and Tegos et al (hereinafter “Tegos”).
3. Claims 57-61 are provisionally rejected on the ground on nonstatutory obviousness-type double patenting as being obvious over claims 57-61 of copending Application Serial No. 11/770,136.

Applicant respectfully traverses the rejection. Claim 57 has been cancelled hereinabove and the subject matter of new claim 67 finds support in the example on page 31 of the specification.

Claim 67 now recites a concentration of L-carnitine of 0.25 to 50 mM. The claim is limited to L-carnitine and it clearly specifies that the limit of the storage is 8 days, as shown in the cited

example. Accordingly, the cancellation of claim 57 and the addition of new claim 67 render the rejection under 35 U.S.C. § 112, ¶1 moot. Thus, withdrawal of the rejection of claims 57-61 as allegedly failing to comply with the written description requirement is respectfully requested.

The cited references have been discussed at length during the prosecution of the present application. Therefore, Applicant incorporates by reference the previously submitted arguments and wishes to add the following additional arguments.

Sweeney teaches that the addition of saline, L-carnitine or L-acetylcarnitine at 5 mM to platelet concentrate shows better preservation of pH, less glucose consumption and lactate production after 5 days of storage and suggests a possible role for these compounds in improving the quality of the stored platelets (*e.g.*, page 1315 left column, beginning of the Results section). In addition, Sweeney discloses standard, non-leuko-reduced platelet concentrates.

On the contrary, new claim 67 recites the step of leuko-depleting the platelet concentrates. This step is completely absent in Sweeney and unexpectedly results in the ability to store such platelet concentrates for up to 8 days.

Moreover, Applicant respectfully disagrees with the Examiner's statement on page 8 of this Final Office Action, where it is said that there is not direct comparison between the presently claimed invention and the method disclosed in Sweeney. In the example described on page 31, lines 13-19 of the specification, Applicant refers to the method disclosed in Sweeney. However, a direct comparison of the two methods is completely irrelevant as, contrary to Applicant's, Sweeney's method does not comprise leuko-depleting the platelet concentrates.

Accordingly, for all of the reasons discussed above, Sweeney does not disclose all of the claimed limitation and fails to render obvious the claimed subject matter.

Cavazza discloses the therapeutic use of L-carnitine, lower alkanoyl L-carnitines or the

pharmacologically acceptable salts thereof in combination with resveratrol (*e.g.*, the abstract).

The composition disclosed in Cavazza is directed to the treatment of cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy (*e.g.*, the abstract). However, to rely on a reference under 35 U.S.C. § 103, the reference must be analogous to the subject matter at issue (*e.g.*, MPEP § 2141.01(a)). Thus, Applicant asserts that the treatment of cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy cannot be taken considered to be in the same field of endeavor of the presently claimed platelet storage.

The skilled artisan would be totally unaware of method of treatment cardiovascular disorders, peripheral vascular diseases and peripheral diabetic neuropathy and would not address his attention to Cavazza to try to find a possible suggestion with respect to platelet storage. Thus, Applicant submits that Cavazza fails to provide the missing link in that it suffers from the same defects of Sweeney. Accordingly, the combination of Sweeney with Cavazza still fails to render obvious the claimed subject matter.

Ogawa teaches that prestorage leukocyte filtration reduces the severity of post-transfusion side effects (*e.g.*, last paragraph of left col. on page 108) and discloses a period of storage of 72 hours (*e.g.*, left col., page 104), i.e., three days, a period which is shorter than the storage period disclosed in Sweeney.

Tegos simply describes that glycolytic enzymes are stable for 72 hours, *e.g.*, 3 days, which is a storage period even shorter than the 5 days disclosed in Sweeney (*e.g.*, last three lines of left col. at page 204).

Accordingly, the skilled person would not find any motivation in Ogawa to add a leuko-depletion step to the method disclosed in Sweeney since the period of storage disclosed in Sweeney is longer than the period of storage disclosed in Ogawa. Accordingly, there is no

suggestion or motivation in Ogawa to modify Sweeney to achieve the unexpected results of the presently claimed invention, e.g., the storage of the platelet concentrates for up to 8 days. Further, even if one were to combine the teaching of Ogawa with the teaching of Cavazza, Tegos and Sweeney, a person skilled in the art would not arrive to the presently claimed method because none of the cited documents suggests how to modify the method disclosed in Sweeney to arrive at the presently claimed invention and to the unexpected results claimed herein.

Accordingly, as none of the cited references, either alone or in combination, discloses storing the leuko-depleted platelet concentrates of up to 8 days, it is respectfully submitted that the combination of the cited references would not have rendered obvious the claimed subject matter to one skilled in the art. Thus, withdrawal of the rejection of the pending claims under 35 U.S.C. § 103 (a) as being unpatentable is respectfully requested.

Applicant submits herewith a terminal disclaimer to copending Application Serial No. 11/770,136. Therefore, the nonstatutory obviousness-type double patenting rejection of claim s 57-61 is now moot. Applicant respectfully requests withdrawal of the same.

As such, Applicant respectfully submits that the subject matter of pending claims is allowable and a Notice to that effect is respectfully requested.

This response is being filed within the shortened statutory period for response, thus, no fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. § 1.136(a), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time of its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated

herewith is to be charged to the above-mentioned deposit account.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted

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